

PG4715USw  
Ser. No. 10/510,968

## REMARKS

Claims 1-7, 9-12, and 14-25 are pending in the application before entry of this Amendment. Claims 12 and 14-25 have been withdrawn from consideration due to a restriction requirement. By way of this Amendment, claims 12, and 14-21 are canceled. Rejections posed in the pending Final Office Action are addressed below.

Applicants claim a dry powder pharmaceutical composition for inhalation therapy comprising salmeterol or a pharmaceutically acceptable salt thereof, fluticasone propionate, an excipient, and a derivatized carbohydrate in particulate form wherein the derivatized carbohydrate has an aerodynamic size in the range 1 - 20  $\mu\text{m}$  (see Claim 1).

### Rejections under 35 USC §103

The claimed composition has been rejected under 35 USC §103 as obvious in view of a combination of references. Specifically, the Office has cited EP Patent 0416951A1 to Palmer ("Palmer") as teaching a formulation having salmeterol, fluticasone propionate, and an excipient, in combination with WO Publication 0215876A2 to Blair ("Blair") as teaching the use of derivatized carbohydrates in dry powder inhalers. Neither reference discloses a derivatized carbohydrate with the claimed size range of 1 – 20  $\mu\text{m}$ .

The claimed size range of the derivatized carbohydrate, at least, imparts non-obviousness to the claims. Although claimed ranges can sometimes support a *prima facie* case of obviousness when compared to non-overlapping ranges (MPEP 2144.05(I)), *prima facie* obviousness is not supported when there is some criticality in the claimed range (MPEP 2144.05(III), para. 1) nor when the prior art teaches away from the claimed range (MPEP 2144.05(III), para. 2).

Here, compositions with the claimed size range of derivatized carbohydrates demonstrate surprisingly enhanced stability performance, particularly in respect of eliminating or reducing the detrimental effect on fine particle dose caused on storage of said compositions (p. 2, II. 13-16). The claimed size range is the preferred size range for enhancing stability performance (p.3, II. 24-25), and compositions having derivatized carbohydrates within the claimed size range have been demonstrated to provide decreased reduction in post-storage stage 2 deposition (Ex. 1, blends B – E; Figs. 1 and 2), i.e. significantly reduce the deterioration in fine particle

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fraction following exposure to high temperature and humidity (p.14, l. 14 – p.15, l.6). Thus, there is criticality in the claimed range.

Further, the pending prior art teaches away from the claimed size range. Blair is cited as disclosing the non-overlapping derivatized carbohydrate size range of 30-300  $\mu\text{m}$ . Blair provides no teaching or suggestion that derivatized carbohydrate particles of size less than 30  $\mu\text{m}$  should be used, nor does Blair provide any recognition that derivatized carbohydrate particles could be used to stabilize stored compositions. Rather, Blair teaches that the derivatized carbohydrates are to be used as carriers (p. 2, l. 6), and that the size of the particles is to be greater than 30  $\mu\text{m}$ , more preferably greater than 50  $\mu\text{m}$  (p.3, ll. 33-34). Thus, the pending reference teaches away from the claimed particle size.

Whereas the claimed size range of derivatized carbohydrate particles has been shown to have criticality, and whereas the cited reference has been shown to teach away from the claimed size range, Applicants submit that the claimed size range does not render the claims obvious in view of the prior art.

#### Provisional Obviousness-type Double Patenting Rejection

Claims 1-7 and 9-11 stand provisionally rejected on the grounds of non-statutory obviousness-type double patenting in view of application Ser. No. 10/511,042.

Applicants respectfully request that this rejection be deferred until this application or the reference application is found in condition for allowance.

#### Reply to Examiner's Response to Arguments

In the first response, the Examiner alleges obviousness of the instant invention based on particle sizes disclosed in the instant specification which are larger than the prior art. Applicants direct the Examiner to MPEP 2144.05 and respectfully submit that the guidelines relied upon by the Examiner are based on claimed ranges, not ranges which are merely disclosed but not claimed. Here, the ranges at issue are those claimed by Applicants, the non-obviousness of which is discussed above.

In the second response, the Examiner states that a difference in purpose does not defeat a case for obviousness. However, in the instant application, the reference is not only lacking in stated purpose. As described above, the references fail to disclose the actual claimed range, the criticality of

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the claimed range, or any suggestion or motivation to include the claimed range. If anything, the references teach away from the claimed range by preferring larger particles for the intended use as carriers. Thus, it is not the case that Applicants were lead to a common size range with only a different purpose in mind, as implied by the Examiner. Rather, Applicants have claimed a unique size range, which was unappreciated and undesired until Applicants invention of their improved dry powder composition.

Request for Rejoinder

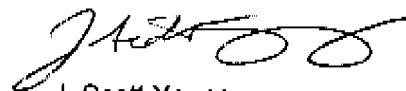
In view of the pending restriction requirement, and in anticipation of a Notice of Allowance, Applicants have canceled claims 12, and 14-21. Applicants reserve all right to file these finally restricted claims in a divisional application.

The pending claims having been shown to be allowable, Applicants respectfully request the rejoinder of claims 22-25 under 37 CFR 1.475.

Conclusion

In conclusion, Applicants respectfully submit that the currently withdrawn claims are in proper condition for rejoinder and that all the claims of the application are in condition for allowance, which action is respectfully requested. The Examiner is invited to contact the undersigned at (919) 483-8160, to discuss this case, if desired.

Respectfully submitted,



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Date: Aug 23 2007  
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